REMARKS

Claims 1-3, 6-7 and 13-14 are pending.

Applicant would like to thank the Examiner for the interview on August 26, 2010.

Claims 1, 3, 5, 13 and 14 stand rejected under 35 U.S.C. 102 (b) as anticipated by Okada et al. (US 6,455,053). Claims 1, 3, 13 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by DuRoss (US 5,075,291). Claims 1-3, 6, 7, 13 and 14 stand rejected under 35 U.S.C. 103(a) as unpatentable over Okada et al. Claims 1-3, 13 and 14 stand rejected under 35 U.S.C. 103(a) as unpatentable over DuRoss in view of Okada et al.

Applicant respectfully requests reconsideration and allowance of all pending claims in view of the remarks set forth below.

Anticipation Rejections

The rejection of Claims 1, 3, 5, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053) is maintained for the reasons of record. The Examiner stated that Okada et al. discloses a pharmaceutical dosage form comprising a drug and a matrix adjuvant (erythritol) in a ratio which falls within the ratio claimed. *See* Office Action dated 07-29-08, at par. 8. Rejection of Claims 1, 3, 13 and 14 under 35 U.S.0 102(b) as being anticipated by DuRoss (US 5,075,291) is maintained for the reasons of record. The Examiner stated that DuRoss discloses compositions comprised of a pharmaceutical active ingredient and sorbitol as the matrix adjuvant in a ratio which falls within the ratio claimed. *See* Office Action dated 07-29-08, at par. 4. Regarding the use of the term "drop pill," the Examiner indicated that even if the preamble is afforded patentable weight, Applicant has not demonstrated that the different processes result in products which are different and non-obvious. *See* Office Action dated 01-30-09, at page. 4.

Applicant respectfully disagrees.

First, Applicant herewith submits an additional declaration by Dr. Chen Jianming ("*Jianming Declaration III*"), which in combination with the prior declarations by Dr. Chen Jianming, submitted on January 11, 2010 ("*Jianming Declaration I*") and June 14, 2010 ("*Jianming Declaration II*") demonstrates that the process of the present application is different from the process in the cited references and results in products that are different and non-obvious from the prior art. Thus, the limitation of "drop pill" in the preamble term should be considered and the Examiner should consider the entirety of the claim.

Claim 1 recites:

> 1. A drop pill comprising a pharmaceutical active ingredient and at least one pharmaceutically acceptable matrix adjuvants selected from a group consisting of D-ribose, fructose, glucose, xylose, trehalose, raffinose, maltose, gelose, sucrose ester, D-ribonic acid-γ-lactone; erythritol, sorbitol, xylitol, arabitol, isomaltitol, lactitol, malic acid, citric acid; said drop pill is prepared by dripping a solution, suspension, or emulsion of said pharmaceutical active ingredient with said at least one pharmaceutically acceptable matrix adjuvant into a coolant.

To anticipate a claim, a reference must disclose, either explicitly or inherently, each and every claim limitation. MPEP §2131; *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 recites a "drop pill" and a process of making the "drop pill" by "dripping" a solution, suspension, or emulsion of the drug and the adjuvant into a "coolant." *Okada et al.* does not disclose a "drop pill" or "dripping" into a "coolant." Thus, *Okada et al.* does not disclose every element of claim 1, either explicitly or inherently as required under *Verdegaal Bros.*

Further, Applicant has shown that the structure and properties of the product of *Okada et al.* are different than the claimed drop pill of the present application, and has demonstrated that the different processes result in products which are different. As

shown in the declarations by Dr. Chen Jianming, the drop pill as claimed in the present application is clearly different from the product of *Okada et al.* *Okada* et al. discloses pharmaceutical product formulations, which are clearly not "drop pills." What is disclosed in *Okada et al.* is a rapidly dissolving molded dosage form produced by mixing a drug and a matrix adjuvant into a suspension, then charging the suspension in a mold, and air-drying the resulting composition. The resulting formulation is a solid product which will rapidly disintegrate and dissolve (See *Okada, et al. e.g.*, Col. 1, lines 1-2 and Examples 9 and 12). The submitted declarations demonstrate that the product claimed in the present application is clearly different from the product of *Okada et al.* The product of the present application is harder, has a significantly longer disintegration time, has higher density and a smoother surface than the product of *Okada et al.* (*See "Jianming Declaration I"* paragraphs 6-9 and "*Jianming Declaration II*" paragraphs 6-8). Thus,

DuRoss does not disclose a "drop pill" ...prepared by "dripping ... into a coolant." Thus, DuRoss does not disclose every element of claim 1, either explicitly or inherently as required under *Verdegaal Bros.*

In addition, as shown in the declarations by Dr. Chen Jianming, submitted on January 11, 2010 ("*Jianming Declaration I*") and June 14, 2010 ("*Jianming Declaration II*"), the drop pill as claimed in the present application is clearly different from the product of *DuRoss.* *DuRoss* discloses a product which is prepared by forming a molten sugar alcohol, dispersing particles of a pharmaceutically active material in the molten sugar alcohol followed by cooling under agitation and cooling slowly until the sugar alcohol is fully crystallized. The resulting product is a crystalline sugar alcohol having dispersed within its crystal matrix particles of the pharmaceutically active compound which may be ground to provide a powder that can be formed into tablets. (See specification at col. 4, lines 58-60). Thus, the resulting product is clearly different from the claimed "drop pill." The Examiner's attention is directed to paragraphs 14-17 of the "*Jianming Declaration I"* which includes evidence that the claimed invention yields a drop pill which is different than the product of DuRoss. As shown in the "*Jianming Declaration* I" the drop pills of the present application

and DuRoss's product have different crystalline states. Further, the dissolution percentage of the drop pill as claimed in the '078 application is higher than that of the DuRoss product. Thus, Applicant has shown that the structure and properties of the product of DuRoss are different than the claimed drop pill of the present application, demonstrating that the different processes result in products which are different.

In the Advisory Action dated July 6, 2010, the Examiner further stated that the comparison data submitted with the Declarations by Dr. Chen Jianming is not found to be persuasive because the drop pill methodology used to prepare the drop pills in accordance with the instant invention is much narrower than any of the product-by-process limitations found in the claims. Applicant would like to emphasize that comparative tests were performed in order to demonstrate that the invention produced a product with properties not possessed in the prior art. Thus, identical components were used with the only variant being the method of production. Therefore the comparative tests necessarily required narrower limitations than the limitations found in the claims.

On the basis of the foregoing, Applicant respectfully submits that claim 1 and dependent claims are not anticipated by *Okada et al.* or *DuRoss*. Withdrawal of the anticipation rejection of independent claim 1 and dependent claims, 3, 5, 13 and 14 over *Okada et al.* and independent claim 1 and dependent claims 3, 13 and 14 over *DuRoss* is respectfully requested.

Obviousness Rejection over Okada et al.

Claims 1-3, 6, 7, 13 and 14 stand rejected under 35 U.S.C. 103(a) as unpatentable over Okada et al.

First, to establish a *prima facie* case of obviousness, the Examiner must show that the prior art discloses, teaches or suggest each limitation of the claims at issue, MPEP §2143.03, or at least provides an "apparent reason" to modify the prior art in the direction of the claimed invention. *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007). Second,

to establish a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have a reasonable expectation of success to modify *Okada* in the direction of the drop pill" of claim 1. MPEP §2143.02.

The object of the present application is to provide a drop pill which is synthesized using natural materials rather than the previously used synthetic matrix adjuvants such polyethylene glycol. (*See* Specification at page 5, third paragraph). Such synthetic matrix adjuvants in addition to being incompatible with many drugs lead to toxic and side effects. (*See* Specification at page 6, first paragraph). Substitution of such synthetic matrix adjuvants was a difficult task since after the matrix adjuvant was changed the drop pills were difficult to prepare. (*See* Specification at page 6, third paragraph). Thus, the inventors set out to find, a novel method of preparing drop pills using safe and nontoxic matrix adjuvants derived from plants. (See Specification at page 7, first paragraph).

First, as shown above, Okada et al. does not disclose every limitation of the claims at issue. Second, one skilled in the art would have no apparent reason to modify the teachings of Okada et al. to arrive at the drop pill of the claimed invention. The objective of Okada et al. is to provide solid preparation which disintegrates and dissolves rapidly. See Okada et al., column 1, lines 66-67 to column 2, line 1. To achieve the rapidly dissolving product the Okada et al. process requires, *inter alia*, removal of moisture or solvent from the mixture, and evaporation during formation of the solid. This results in many micro-pores being produced during the preparation. As a result, the preparation disclosed by Okada et al. produces a product that is loose in structure with many micro-pores, capable of rapid dissolution. In contrast, in the process claimed in the present application, no evaporation or sublimation occurs during the formation of a drop pill, and thus, no micro-pores are produced. Finally, since the preamble is limiting, the Examiner is respectfully requested to point out why one skilled in the art would have an expectation of success based on the disclosure of *Okada et al.*

Hence, the Examiner has not established a *prima facie* case of obviousness.

Moreover, Applicant surprisingly found advantages over the rapidly dissolving preparation disclosed by Okada et al. For example, the claimed drop pills of the present application are denser and have a slower disintegration time, resulting in a product that is more resistant to pressure, is easier package, transport and store. Applicant herewith submits a new Declaration of Dr. Chen Jianming ("Jianming Declaration III"). The *Jianming Declaration III* is submitted as evidence in further response to Examiner's allegations of *prima facie* obviousness. The *Jianming Declaration III* is submitted to show absence of *prima facie* obviousness, not in rebuttal of the alleged *prima facie* case. In the *Jianming Declaration III*, Dr. Jianming unequivocally states one skilled in the art would not expect the properties obtained by using the process and the selected matrix adjuvants as claimed in the present application. Particularly, Dr. Jianming underscores that an artisan, having available the information in the art, would not expect to obtain a drop pill having an average hardness that is higher, a significantly longer average disintegration time, a higher density and a smoother surface as compared to the product of Okada et al (*See* paragraph 13).

Applicant respectfully asserts that the "*Jianming Declaration III*" is un-rebutted evidence of non-obviousness, and it provides further support for non-obviousness. Applicant respectfully suggests the Examiner has not put forth a *prima facie* case of obviousness with respect to claim 1 and dependent claims 2-3, 6, 7, 13 and 14.

Withdrawal of the obviousness rejection of claims 1-3, 6, 7, 13 and 14 over Okada et al. is respectfully requested.

Obviousness Rejection Over DuRoss in view of Okada et al.

Claims 1-3, 13 and 14 stand rejected under 35 U.S.C. 103(a) as unpatentable over DuRoss in view of Okada et al.

First, as shown neither *DuRoss* nor *Okada et al.,* alone or in combination teach, disclose or suggest every limitation of the claims at issue. Furthermore, one skilled in the art would have no "apparent reason" to modify the teachings of DuRoss in the direction of the claimed invention. DuRoss discloses a process for the controlled crystallization of a melt, wherein the melt (consisting of the pharmaceutical active ingredient and a sugar alcohol) is placed on a tray to dry and slowly cooling until crystallized. The product of DuRoss has to be further modified to provide a powder that can be make into tablets. *Okada et al.* discloses a method of producing a rapidly dissolving product wherein a suspension of the active and saccharide are charged into a mold and air-dried followed by additional slow drying. Furthermore, modification of the process of *DuRoss* with the teachings of *Okada et al.* would not result in the formation of the drop pill as claimed in the present application. Thus, one skilled in the art would simply have no reasonable expectation of obtaining the drop pill of the rejected claims by modifying the process of DuRoss with the extract of Okada et al.

Applicant herewith submits a Declaration by Dr. Chen Jianming ("*Jianming Declaration III*"). The *Jianming Declaration III* is submitted as evidence in further response to Examiner's allegations of *prima facie* obviousness. The *Jianming Declaration III* is submitted to show absence of *prima facie* obviousness, not in rebuttal of the alleged *prima facie* case. In the *Jianming Declaration III*, Dr. Jianming unequivocally states one skilled in the art would not expect the properties obtained by using the process in combination with the selected matrix adjuvant as claimed in the present application. Particularly, Dr. Jianming underscores that an artisan, having available the information in the art, would not expect to obtain a drop pill having an average hardness that is higher, a significantly longer average disintegration time, a higher density and a smoother surface as compared to the product of Okada et al and different crystalline state and different dissolution rates as compared to the product of DuRoss. (*See* paragraph 13).

Applicant respectfully asserts that the "*Jianming Declaration III*" is un-rebutted

evidence of non-obviousness, and it provides further support for non-obviousness. Applicant respectfully suggests the Examiner has not put forth a *prima facie* case of obviousness with respect to claim 1 and dependent claims 2-3, 13 and 14.

On the basis of the foregoing, Applicant respectfully submits that claim 1 and dependent claims 2-3, 13 and 14 are non-obvious over DuRoss in view of Okada et al. Withdrawal of the rejection is respectfully requested.

The Applicant therefore respectfully requests reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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